K031216

C. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

[in Accordance with SMDA of 1990]

MonoPlus Poly-p-dioxanone absorbable suture

April 18, 2003

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

CONTACT: Georg Keller
800-258-1946 x 5073 (phone)
610-791-6882 (fax)

TRADE NAME: MonoPlus Poly-p-dioxanone monofilament absorbable surgical suture

COMMON NAME: Synthetic Absorbable Surgical Suture

DEVICE CLASS: Class II

PRODUCT CODE: 79NEW

CLASSIFICATION: 878.4840 – Suture, surgical, absorbable , polydioxanone

REVIEW PANEL: General & Plastic Surgery

INDICATIONS FOR USE

MonoPlus Poly-p-dioxanone absorbable suture are indicated for use in general soft tissue approximation and/or ligation, especially in cases where an extended wound support of more than 4 weeks is desirable. MonoPlus can also be used in paediatric cardiovascular surgery. Not to be used in adult cardiovascular tissue, microsurgery and neural tissue.

DEVICE DESCRIPTION

The subject device is an absorbable, flexible monofilament suture thread which is supplied sterile. It is composed of a synthetic Poly (p-dioxanone), and it is indicated for soft tissue approximation and/or ligation, especially in cases where an extended wound support of more than 4 weeks is desirable. MonoPlus can also be used in paediatric cardiovascular surgery. Not to be used in adult cardiovascular tissue, microsurgery and neural tissue. It will be offered undeyed with the FDA approved colorant D&C Violet No.2 in accordance with Title 21 CFR, §74.3602. It is available uncoated, and will be available with or without standard needles attached.

PURPOSE FOR SUBMISSION

This submission seeks marketing clearance for Aesculap's MonoPlus Poly-p-dioxanone absorbable suture.

PERFORMANCE DATA

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices.

SUBSTANTIAL EQUIVALENCE

Aesculap® Inc. believes that MonoPlus Poly-p-dioxanone monofilament absorbable surgical suture is substantially equivalent to:

- Ethicon, Inc.; PDS II Polydioxanone Suture (N18331)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2003

Mr. Georg Keller
Regulatory Affairs Manager
Aesculap, Inc.
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K031216
Trade/Device Name: MonoPlus Poly-p-dioxanone absorbable suture
Regulation Number: 21 CFR 878.4840
Regulation Name: Suture, surgical, absorbable, polydioxanone
Regulatory Class: II
Product Code: NEW
Dated: April 16, 2003
Received: May 6, 2003

Dear Mr. Keller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B. INDICATIONS FOR USE STATEMENT

510(k) Number: K031216

Device Name: **MonoPlus Poly-p-dioxanone absorbable suture**

Indication for Use:

MonoPlus Poly-p-dioxanone absorbable sutures are indicated for use in general soft tissue approximation and/or ligation, especially in cases where an extended wound support of more than 4 weeks is desirable. MonoPlus can also be used in pediatric cardiovascular surgery. Not to be used in adult cardiovascular tissue, microsurgery and neural tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the-Counter Use _____

(per 21 CFR 801.109)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031216